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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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October 21, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Herbert B. Tully
President
Wilbur-Ellis Company
345 California Street, 27th Floor
San Francisco, CA 94120

Ref#: Den-03-03

Dear Mr. Tully:

Representatives from the U.S. Food and Drug Administration (FDA) and Utah Division of Animal Feeds (UDAF) inspected Knox McDaniel Company in Ogden, Utah on May 8, 2002. The inspection was in follow up to the recent deaths of several dairy cows at ~~X X X X X X~~ Utah, due to acute selenium poisoning (selenosis).

During the inspection, FDA collected a sample of Capener Custom Anionic Mineral Premix, lot #87349, manufactured by Knox McDaniel Company, Ogden, Utah, on March 25, 2002, and found it to contain an average of 1152 parts per million (ppm) selenium in 2 subsamples rather than the labeled amount of 13.25 ppm. This premix is adulterated within the meaning of section 402(a)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act (the Act) because it is not in conformance with the food additive approval for selenium in animal feed and drinking water, 21 CFR 573.920, and therefore contains an unsafe food additive. For example, the lowest tested level found the premix to contain 910 ppm of selenium, or 413.6 mg/lb. However, under 21 CFR 573.920(d)(1), selenium must be incorporated into each ton of complete feed by adding no less than 1 pound of premix containing no more than 272.4 mg/lb. of added selenium. In addition, the inspection found significant deviations from the manufacturing practices requirements set forth in 21 CFR 573.920(e). A copy of 21 CFR 573.920 is included for your information and use.

You should ensure that the label or labeling of your selenium premix contains this information.

The above is not intended as an all-inclusive list of violations. As a manufacturer of medicated and non-medicated feeds, including mineral premixes, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law. We note that your firm has changed its procedures for flushing the system after a high concentration of selenium is mixed. You should promptly take any additional action necessary to correct the above violations and to ensure that such violations do not recur. Failure to make immediate and lasting corrections may result in regulatory action without further notice, which could include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the current status of your corrective actions and the specific steps you have taken to correct the noted violations. Your response should be directed to H. Tom Warwick, Compliance Officer, at the letterhead address.

Sincerely,

B. Belinda Collins
Director, Denver District